

- Q2
- a) incubating a sample whereby said sample contains nucleic acids with a nucleic acid probe which is selected from the group consisting of:
- (i) the nucleic acid shown in SEQ ID NOS:1, 3 or 5 or a nucleic acid which is complementary thereto; and
 - (ii) nucleic acids which hybridize with one of the nucleic acids from (i) and
- b) detecting the hybridization by means of a further binding partner of the nucleic acid of the sample and/or the nucleic acid probe.

Please add new claim 10 as follows:

Q3

--10. The method of claim 3 wherein the detection of a nucleic acid molecule encoding an IIP-gene correlates to detecting tumor cell proliferation, survival and escape of apoptosis.--

REMARKS

Claims 3 to 7 and 10 are pending in this application.

Claims 3-7 are rejected.

Claim 3 is amended herein.

Claim 10 is added herein.

Informalities

The Examiner objected to the disclosure since an application referred therein has matured into a U.S. patent. Applicants have amended the disclosure to reflect that the application cited therein has matured into a patent.

Claim Rejection

Claims 3-7 stand rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such as way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

While not acquiescing to the merit of the rejection of the claims under 35 U.S.C. 112, first paragraph, applicants have amended the claims to recite "A method for the detection of a nucleic acid molecule encoding an IIP-gene." Although the application provides disclosure regarding a method for detecting proliferation of a cancer cell, the portion of the disclosure directed to the diagnostic method steps specifically provides for detecting a nucleic acid molecule encoding an II-P gene. (See, Specification, p. 16, line 31 to p. 17, line 29, specifically, p. 16, lines 32-33). However, there is support that detecting II-P genes correlates with detecting tumor cell proliferation, survival and escape of apoptosis. (See, for example, Specification, p. 4, lines 5-6). Accordingly, new claim 10 provides for the detection of tumor cell proliferation, survival and escape of apoptosis. No new matter is added in the claim amendments.

With regard to the condition for hybridization, applicants submit that there is adequate description in the specification to enable a person skilled in the art to make and/or use the invention. Although the disclosure provide methods of nucleic acid hybridization, in-situ hybridization, dot or slot hybridization and diagnostic techniques that is known by the skilled artisan, the disclosure also provides for specific hybridization conditions in this particular application regarding the aspect of the methods of claims 3 to 7 and 10, as shown in Example 6 therein. (See, Specification, page 29, lines 9 to 15). Thus, applicants submit that the claims regarding hybridization is enabling.

Accordingly, applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, first paragraph rejection to claim 3-7.

Claims 3-7 also stand rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. As provided above, the hybridization steps are provided in the disclosure in sufficient detail in Example 6. (See,

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Specification, page 29, lines 9 to 15). Thus, applicants submit that the essential steps for hybridization are adequately provided therein.

Accordingly, applicants respectfully request reconsideration and withdrawal of the 35 U.S.C. 112, second paragraph rejection to claim 3-7.

With the amendment and remarks herein, applicants believes that this application is in condition for allowance, and respectfully request a notice of allowance at an early date. Should the Examiner believe a discussion is helpful to expedite prosecution and put this application in a form for allowance, applicants invite the Examiner to contact the undersign at the telephone exchange below.

No further fee is believed to be due, but if any fee is in fact be due, the Commissioner is authorized to charge the amount of any fee to Deposit Account No. 08-2525.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

IN THE SPECIFICATION:

After the Title:

This is a divisional of copending application Serial No. 09/453,195, filed December 2, 1999, now U.S. Patent No. 6,368,826.

IN THE CLAIMS:

3. (Amended) A method for the detection of ~~the proliferation potential of a cancer cell~~ a nucleic acid molecule encoding an IIP-gene comprising

a) incubating a sample whereby said sample contains nucleic acids with a nucleic acid probe which is selected from the group consisting of:

(i) the nucleic acid shown in SEQ ID NOS:1, 3 or 5 or a nucleic acid which is complementary thereto; and

(ii) nucleic acids which hybridize with one of the nucleic acids from (i) and

b) detecting the hybridization by means of a further binding partner of the nucleic acid of the sample and/or the nucleic acid probe.

--10. (New) The method of claim 3 wherein the detection of a nucleic acid molecule encoding an IIP gene correlates to detecting tumor cell proliferation, survival and escape of apoptosis.--